REMARKS

Reconsideration of this application is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 22-25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. The Examiner contends that no restriction map or nucleotide sequence of pROD 4.7 (accession number I-627) was provided. The Examiner dismisses applicants' arguments stating: "None of the passages relied upon disclose the preparation of HIV-2ROD polypeptide fragments from the deposited genome." (Office Action at 4-5.) Applicants traverse the rejection.

The Court of Appeals for the Federal Circuit has recently held that inclusion of a nucleotide sequence in a patent application is not required to fulfill the written description requirement of 35 U.S.C. § 112, first paragraph, if a biological deposit of the nucleic acid material has been made. *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1326, 63 U.S.P.Q.2d 1609, 1614 (Fed. Cir. 2002)("reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement."). Applicants have made such a biological deposit.

The specification describes a clone (λ ROD 4) containing the "complete genome" of HIV-2. (Specification at 14, lines 3-5.) The specification further indicates that the λ ROD 4 fragment containing the genome of HIV-2 can be found in plasmid pROD4.7 in *E. coli* deposited under C.N.C.M. No. I-627. (*Id.* at 14, lines 8-10.) Thus, the

specification indicates that plasmid pROD4.7 contains the complete genome of HIV-2, and that the deposited *E. coli* strain contains the plasmid. Accordingly, applicants had possession of the complete genome of HIV-2. As in *Enzo*, applicants' reference in the specification to the deposit of pROD 4.7 describes the sequence of this HIV-1 clone sufficiently to the public for purposes of meeting the written description requirement. *See Enzo*, 296 F.3d at 1326, 63 U.S.P.Q.2d at 1614. In *Enzo*, the court stated:

> A person of skill in the art, reading the accession numbers in the patent specification, can obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the nucleotide sequences from the deposited organisms containing those sequences.

Id. The same is true in the present case. Applicants' claimed fragments can be excised from the deposited plasmid by following the techniques described in applicants' specification. Consequently, the Examiner's reliance on the lack of nucleotide sequence information in the specification to support the rejection is in error.

Moreover, **applicants provided a restriction map of the complete genome of HIV-2** (and λ ROD 4). (Specification at Fig. 3A.) The restriction map shows the sites for *Bam*HI, *Eco*RI, *Hin*dIII, *Kpn*I, *Pst*I, *Pvu*II, *Sac*I, and *Xba*I. (*Id.*) Since pROD4.7 contains the complete genome of HIV-2 from λ ROD 4, the specification provides a restriction map of the complete genome of HIV-2 in pROD4.7. Thus, the Examiner's assertion to the contrary is incorrect.

Based on applicants' disclosure of the restriction map of the complete genome of HIV-2 and its deposit, the skilled artisan would recognize that applicants had possession of nucleic acid fragments of HIV-2 encompassing the complete genome. Based on the further teachings of the specification, the skilled artisan would also

understand that applicants' had possession of the claimed method of using HIV-2 nucleic acid fragments to produce HIV-2 peptides.

For example, **the specification explicitly teaches that polypeptides can be produced by expression of HIV-2 sequences** in hosts, such as bacteria, yeast, or animal cells:

> In addition, the genetic sequences of the HIV-2 virus may be used to create the polypeptides encoded by these sequences. Specifically, these polypeptides may be created by expression of the cDNA obtained according to the teachings herein in hosts such as bacteria, yeast or animal cells.

(Specification at 17, lines 21-25.) The Examiner's allegation that applicants' specification does not disclose the preparation of HIV-2 polypeptide fragments from the deposited genome is in error.

In addition, the specification describes cloning cDNAs into a vector. (*Id.* at 12, lines 5-6.) The specification describes hybridization of the inserts of cDNA clones under the claimed hybridization conditions to detect HIV-2 cDNAs. (*Id.* at 19, line 19, through 20, line 22.) Thus, applicants' specification describes the claimed method for producing HIV-2 peptides.

Moreover, the specification describes the cross-hybridization between the HIV-1 and HIV-2 genomes. (*Id.* at 14-15, bridging paragraph, and Fig. 3B.) In this way, the specification identifies genes (*e.g.*, *gag* and *pol*) within the HIV-2 genome. (*See* Fig. 3B.) Thus, based on applicants' disclosure, the skilled artisan would understand that applicants' HIV-2 genome encoded HIV-2 peptides.

Following applicants' disclosure, the skilled artisan is instructed to clone and express pROD4.7 nucleic acid fragments encoding HIV-2 peptides using applicants'

claimed method. Thus, the skilled artisan would recognize that applicants had possession of the claimed method. Accordingly, applicants respectfully request withdrawal of the rejection.

Once again, the Examiner alleged that applicants' clone may be "defective in one or more locations and replication-impaired." (Office Action at 4.) Applicants traverse this assertion. There is no evidence of record to support this assertion. If the Examiner is relying on personal knowledge to support this allegation, applicant's request that the Examiner provide an affidavit or declaration in support of this allegation. *See* 37 C.F.R. § 1.104(d)(2).

Applicants respectfully submit that this application is in condition for allowance. In the event that the Examiner disagrees, he is invited to call the undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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By: _____

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